



PATENT
Attorney Docket No. 212241

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Ts'o et al.

Application No. 09/888,164

Filed: June 22, 2001

For: **LIGANDS TO ENHANCE CELLULAR
UPTAKE OF BIOMOLECULES**

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
Washington, D.C. 20231

Pursuant to 37 CFR 1.97 and 1.98, the references listed on the enclosed Form PTO-1449 and/or Substitute Form PTO-1449 ("Form 1449") are submitted for consideration by the Examiner in the examination of the above-identified patent application.

The full consideration of the references in their entirety by the Examiner is respectfully requested and encouraged. Also, it is respectfully requested that the references be entered into the record of the present application and that the Examiner place his or her initials in the appropriate area on the enclosed Form 1449, thereby indicating the Examiner's consideration of each of the references.

The submission of the references listed on the Form 1449 is for the purpose of providing a complete record and is not a concession that the references listed thereon are prior art to the invention claimed in the patent application. The right is expressly reserved to establish an invention date earlier than the above-identified filing date in order to remove any reference submitted herewith as prior art should it be deemed appropriate to do so.

Further, the submission of the references is not to be taken as a concession that any reference represents art that is relevant or analogous to the claimed invention. Accordingly, the right to argue that any reference is not properly within the scope of prior art relevant to an examination of the claims in the above-identified application is also expressly reserved.

The Information Disclosure Statement is being filed:

- ☒ **within** any one of the following time periods: (a) within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d); (b) within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 of an international application; (c) before the mailing date of a first Office Action on the merits; or (d) before the mailing of a first Office Action after the filing of a request for continued examination under 37 CFR 1.114.

- ☐ **after** (a), (b), (c) or (d) above, but before the mailing date of a final action under 37 CFR 1.113, a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and includes *one* of:
- ☐ the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below).
- or*
- ☐ the fee of \$180 set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a final action under 37 CFR 1.113 or a Notice of Allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and on or before payment of the issue fee, and includes the Statement under 37 CFR 1.97(e) (see "Statement under 37 CFR 1.97(e)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).
- ☐ **after** the mailing date of a Notice of Allowance under 37 CFR 1.311, and on or before payment of the issue fee, and **within** thirty days of receiving each item of information contained in the Information Disclosure Statement, and includes the Statement under 37 CFR 1.704(d) (see "Statement under 37 CFR 1.704(d)" below), and the fee of \$180 as set forth in 37 CFR 1.17(p) (see "Fees" below).

NOTE: This is for original applications except applications for a design patent, filed on or after May 29, 2000, wherein a paper containing only an Information Disclosure Statement in compliance with 37 CFR 1.97 and 1.98 is being filed.

Copies of the References

- ☒ Copies of the references listed on the enclosed Form 1449 are enclosed herewith. Attached to each reference not in the English language is a concise explanation of the relevance pursuant to 37 CFR 1.98(a)(3).
- ☐ A copy of the foreign search report is enclosed herewith.
- ☐ The references listed on the enclosed Form 1449 were previously identified in the parent application(s) of the present application, and copies of the references were furnished at that time. Accordingly, additional copies of the references are not submitted herewith, so as not to burden the file with duplicate copies of references. The Examiner is respectfully requested to carefully review the references in accordance with the requirements set out in the Manual of Patent Examining Procedure. In accordance with 37 CFR 1.98(d), the details of the parent application(s) relied upon for an earlier filing date under 35 USC 120 in which copies of the references were previously furnished are set out below:

U.S. APPLICATIONS		Status (<i>check one</i>)		
U.S. APPLICATIONS	U.S. FILING DATE	PATENTED	PENDING	ABANDONED
1.				
2.				
3.				

Statement under 37 CFR 1.97(e)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.
- ☐ The **undersigned** hereby states that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application, and, to the knowledge of the undersigned after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

Statement under 37 CFR 1.704(d)

- ☐ The **undersigned** hereby states that each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and that this communication was not received by any individual designated in 37 CFR 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.

Fees

- ☒ No fee is owed by the applicant(s).
- ☐ The **IDS Fee of \$180** under 37 CFR 1.17(p) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$.
- ☐ Charge Deposit Account No. 12-1216 in the amount of \$. (A duplicate copy of this communication is enclosed for that purpose.)

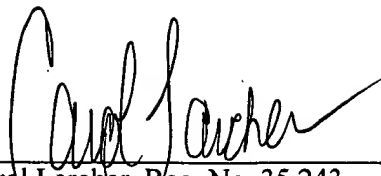
Authorization to Charge Additional Fees

- ☒ If any additional fees are owed in connection with this communication, please charge Deposit Account No. 12-1216. (A duplicate copy of this communication is enclosed for that purpose.)

In re Appln. of Ts'o et al.
Application No. 09/888,164

Instructions as to Overpayment

☒ Credit Account No. 12-1216.
☐ Refund



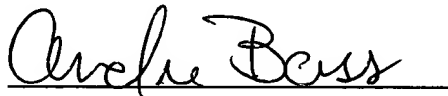
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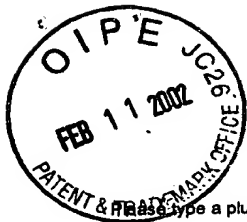
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CERTIFICATE OF MAILING

I hereby certify that this INFORMATION DISCLOSURE STATEMENT (along with any documents referred to as being attached or enclosed) is being deposited with the United States Postal Service via First Class Mail to Addressee in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231

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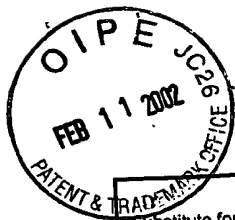
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	09/888,164
				Filing Date	June 22, 2001
				First Named Inventor	Ts'o et al.
				Group Art Unit	
Examiner Name					
Sheet	1	of	6	Attorney Docket Number	212241

U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date if Appropriate
		Application or Patent Number	Kind Code			
	AA	4,415,732		Caruthers et al.	11/15/1983	
	AB	4,671,958		Rodwell et al.	6/9/1987	
	AC	4,680,338		Sundoro	7/14/1987	
	AD	4,725,677		Köster et al.	2/16/1988	
	AE	4,770,183		Groman et al.	9/13/1988	
	AF	4,827,945		Groman et al.	5/9/1989	
	AG	4,952,394		Senter	8/28/1990	
	AH	4,975,278		Senter et al.	12/4/1990	
	AI	5,006,652		Cullinan et al.	4/9/1991	
	AJ	5,010,176		Barton	4/23/1991	
	AK	5,017,693		Hylarides et al.	5/21/1991	
	AL	5,028,697		Johnson et al.	7/2/1991	
	AM	5,087,616		Myers et al.	02/11/1992	
	AN	5,094,849		Cullinan et al.	3/10/1992	
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	AT	5,149,794		Yatvin et al.	9/22/1992	
	AU	5,169,933		Anderson et al.	12/8/1992	
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	BH	5,490,991		Enriquez et al.	2/13/1996	
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	BJ	5,495,006		Climie et al.	2/27/1996	
	BK	5,554,386		Groman et al.	9/10/1996	
	BL	5,563,250		Hylarides et al.	10/8/1996	
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Examiner Signature	Date Considered
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 2 Of 6

Application Number 09/888,164
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Group Art Unit
Examiner Name

Attorney Docket Number 212241

U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document Application or Patent Number	Kind Code	Name of Patentee or Applicant	Date of Publication	Filing Date if Appropriate
	BS	5,639,633		Callstrom et al.	6/17/1997	
	BT	5,646,298		Powell	7/8/1997	
	BU	5,663,321		Gmeiner et al.	9/2/1997	
	BV	5,665,358		Barton et al.	9/9/1997	
	BW	5,679,323		Menz et al.	10/21/1997	
	BX	5,681,811		Ekwuribe	10/28/1997	
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	CA	5,741,900		Gmeiner et al.	4/21/1998	
	CB	5,773,435		Kadow et al.	6/30/1998	
	CC	5,789,248		Fodstad et al.	8/4/1998	
	CD	5,840,674		Yatvin et al.	11/24/1998	
	CE	5,846,728		Haralambidis et al.	12/8/1998	
	CF	5,880,097		Lyttle et al.	3/9/1999	
	CG	5,880,270		Berninger et al.	3/9/1999	
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	CI	5,981,507		Josephson et al.	11/9/1999	
	CJ	5,994,517		Ts'o et al.	11/30/1999	
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	CO	6,063,604		Wick et al.	5/16/2000	
	CP	6,077,837		Kozak	6/20/2000	
	CQ	6,114,520		Hattori et al.	9/5/2000	
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FOREIGN PATENT DOCUMENTS

Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	CS	EP	0 884 327	✓ B1	Florence et al.	3/14/2001		
	CT	PCT	97/20563	✓	Ts'o et al.	6/12/97		
	CU	PCT	00/69473	✓	Vera	11/23/2000		
	CV	PCT	01/32623	✓ A1	Ruggner et al.	5/10/2001		
	CW							
	CX							

OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No
	CY	AGRAWAL et al., "Oligodeoxynucleoside Phosphoramidates and Phosphorothioates as Inhibitors of Human Immunodeficiency Virus," <i>Proc. Natl. Acad. Sci. USA</i> , 85(19):7079-7083 (1988) Abstract Only.		

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OTHER - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city - and/or country where published.	Translation	
			Yes	No
K	CZ ✓	AGRIS et al., "Inhibition of Vesicular Stomatitis Virus Protein Synthesis and Infection by Sequence-Specific Oligodeoxyribonucleoside Methylphosphonates," <i>Biochemistry</i> , 25: 6268-6275 (1986).	✓	
X	DA ✓	AKHTAR et al., "Stability of Antisense DNA Oligodeoxynucleotide Analogs in Cellular Extracts and Sera," <i>Life Science</i> , 49: 1793-1801, (1991).		
P	DB ✓	ALT et al., "Core Specific Antisense Phosphorothioate Oligodeoxynucleotides as Potent and Specific Inhibitors of Hepatitis C Viral Translation," <i>Arch. Virol.</i> , 142: 589-599 (1997).		
P	DC ✓	ANDERSSON, "Reduction and Reoxidation of the Disulfide Bonds of Bovine Serum Albumin," <i>Archives of Biochemistry and Biophysics</i> , 133: 277-285 (1969).		
X	DD ✓	ASAYAMA et al., "Synthesis Of Novel Polyampholyte Comb-Type Copolymers Consisting Of A Poly (L-Lysine) Backbone And Hyaluronic Acid Side Chains For A DNA Carrier," <i>Bioconjugate Chem.</i> , 9: 476-481 (1998).		
P	DE -	BIDER et al., "Ligand-induced Endocytosis of the Asialoglycoprotein Receptor: Evidence for Heterogeneity in Subunit Oligomerization," <i>FEBS Lett.</i> 434: 37-41 (1998).		
X	DF -	BIESSEN et al., "Cholesterol Derivative of a New Triantennary Cluster Galactoside Directs Low- and High-density Lipoproteins to the Parenchymal Liver Cell," <i>Biochem. J.</i> , 302: 283-289 (1994).		
f	DG -	BIESSEN et al., "Synthesis of Cluster Galactosides with High Affinity for the Hepatic Asialoglycoprotein Receptor," <i>J. Med. Chem.</i> , 38: 1538-1546 (1995).		
X	DH -	BIESSEN et al., "Cholesterol Derivative of a New Triantennary Cluster Galactoside Lowers Serum Cholesterol Levels and Enhances Secretion of Bile Acids in the Rat," <i>Circulation</i> , 91: 1847-1854 (1995).		
f	DI ✓	BIESSEN et al., "Targeted Delivery of Oligonucleotides to Parenchymal Liver Cells in Vivo," <i>Biochem. J.</i> , 340: 783-792 (1999).		
X	DJ ✓	BIESSEN et al., "Targeted Delivery of Antisense Oligonucleotides to Parenchymal Liver Cells in Vivo," <i>Methods in Enzymology</i> , 314: 324-342 (1999).		
K	DK ✓	BIESSEN et al., "Novel Hepatotrophic Prodrugs of the Antiviral Nucleoside 9-(2-Phosphonylmethoxyethyl) Adenine with Improved Pharmacokinetics and Antiviral Activity," <i>FASEB J.</i> , 14: 1784-1792 (Sept. 2000).		
X	DL ✓	BONFILS et al., "Drug targeting: Synthesis and Endocytosis of Oligonucleotide-Neoglycoprotein Conjugates," <i>Nucleic Acids Res.</i> , 20(17): 4621-4629 (1992).		
P	DM -	BOUSSIF et al., "A Versatile Vector for Gene and Oligonucleotide Transfer into Cells in Culture and in Vivo: Polyethylenimine," <i>Proc. Natl. Acad. Sci. USA</i> , 92: 7297-7301 (1995).		
P	DN	BRETON et al., "Production of Macrophage-derived Cytotoxic Factor by N-[3-[(Carbamoylmethyl)thio]propionylated] Neoglycoproteins," <i>Bioconjugate Chemistry</i> , 2: 16-18 (1991).		
P	DO	BRUIX, "Treatment of Hepatocellular Carcinoma," <i>Hepatology</i> , 25: 259-262 (1997).		
P	DP	BUNNELL et al., "Targeted Delivery of Antisense Oligonucleotides by Molecular Conjugates," <i>Somatic Cell and Molecular Genetics</i> , 18(6): 559-569 (1992).		
P	DQ	CARUTHERS, "Chemical Synthesis of DNA and DNA Analogues," <i>Acc. Chem. Res.</i> 24: 278-284 (1991).		
P	DR	CATTANEO-PANGRAZZI et al., "Cell-cycle Arrest and p53-independent Induction of Apoptosis in Vitro by the New Anticancer Drugs 5-FdUrd-P-FdCydOct and dCydPam-P-FdUrd in DU-145 Human Prostate Cancer Cells," <i>J. Cancer Res. Clin. Oncol.</i> , 126: 247-256 (May 2000).		
f	DS	CHENG et al., "Characterization of an Antineoplastic Glucuronide Prodrug," <i>Biochem. Pharmacol.</i> , 58: 325-328 (1999).		
P	DT	CHIPOWSKY et al., "Synthesis of 1-thioaldosides Having an Amino Group at the Aclycon Terminal," <i>Carbohydrate Res.</i> , 31: 339-346 (1973).		

Examiner Signature

Date Considered



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OTHER - NON PATENT LITERATURE DOCUMENTS

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			Yes	No
X	DU	CHU et al., "Presentation of Ligands on Hydroxylapatite," <i>Bioconjugate Chem.</i> , 8: 103-105 (1997).		
X	DV	CZERWINSKI et al., "Cytotoxic Agents Directed to Peptide Hormone Receptors: Defining the Requirements for a Successful Drug," <i>Proc. Natl. Acad. Sci. USA</i> , 95: 11520-11525 (1998).		
X	DW	DUFF et al., "Intrabody Tissue-Specific Delivery of Antisense Conjugates in Animals: Ligand-Lihner-Antisense Oligomer Conjugates," <i>Methods in Enzymology</i> , 313: 297-321 (1999).		
X	DX	EICHLER et al., "Studies on the Uptake of Low Molecular Weight Monomeric Tris-galactosyl Conjugates by the Rat Liver," <i>Biochem. Pharmacol.</i> , 44(11): 2117-2122 (1992).		
X	DY	FINDEIS et al., "Ligand-Based Carrier Systems for Delivery of DNA to Hepatocytes," <i>Methods in Enzymology</i> , 247: 341-351 (1994).		
X	DZ	FINDEIS, "Stepwise Synthesis of a GalNAc-Containing Cluster Glycoside Ligand of the Asialoglycoprotein Receptor," <i>Int. J. Peptide Protein Res.</i> , 43: 477-485 (1994).		
X	FA	FRANSSEN et al., "Hepatic and Intrahepatic Targeting of an Anti-Inflammatory Agent with Human Serum Albumin and Neoglycoproteins as Carrier Molecules," <i>Biochem. Pharmacol.</i> , 45(6): 1215-1226 (1993).		
X	FB	GUPTA et al., "Synthesis of Neoglycopeptides and Analyses of their Biodistribution <i>In Vivo</i> to Identify Tissue Specific Uptake and Novel Putative Membrane Lectins," <i>Glycoconjugate J.</i> , 11: 558-571 (1994).		
X	FC	HANGELAND et al., "Cell-type Specific and Ligand Specific Enhancement of Cellular Uptake of Oligodeoxynucleoside Methylphosphonates Covalently Linked with a Neoglycopeptide, YEE(ah-GalNAc) ₃ ," <i>Bioconjugate Chem.</i> , 6: 695-701 (1995).		
X	FD	HARDY et al., "Different Modes of Ligand Binding to the Hepatic Galactose/N-Acetylgalactosamine Lectin on the Surface of Rabbit Hepatocytes," <i>Biochem.</i> , 24: 22-28 (1985).		
X	FE	HUWYLER et al., "Receptor Mediated Delivery of Daunomycin Using Immunoliposomes: Pharmacokinetics and Tissue Distribution in the Rat," <i>JPET</i> , 282: 1541-1546 (1997).		
X	FF	KRIEG et al., "Modification of Antisense Phosphodiester Oligodeoxynucleotides by a 5' Cholesteryl Moiety Increases Cellular Association and Improves Efficacy," <i>Proc. Natl. Acad. Sci. USA</i> , 90: 1048-1052 (1993).		
X	FG	KUO et al., "Novel Systems for Controlled Delivery of Macromolecules," <i>Crit. Rev. Eukaryotic Gene Express.</i> , 6(1): 59-73 (1996).		
X	FH	LEMAITRE et al., "Specific Antiviral Activity of a Poly(L-Lysine)-conjugated Oligodeoxyribonucleotide Sequence Complementary to Vesicular Stomatitis Virus N Protein mRNA Initiation Site," <i>Proc. Natl. Acad. Sci. USA</i> , 84: 648-652 (1987).		
X	FI	LEE, "Synthesis of Some Cluster Glycosides Suitable for Attachment to Proteins or Solid Matrices," <i>Carbohydrate Research</i> , 67: 509-514 (1978).		
X	FJ	LEE et al., "New Synthetic Cluster Ligands for Galactose/N-Acetylgalactosamine-Specific Lectin of Mammalian Liver," <i>Biochem.</i> , 23: 4255-4261 (1984).		
X	FK	LEE et al., "Synthesis of 6'-Aminohexyl 2-Acetamido-2-D oxy-D-Galactoside Isomers and a Unique Isomerization Catalyzed by Ion Exchange Resin," <i>J. Carbohydrate Chemistry</i> , 5(3): 343-357 (1986).		
X	FL	LEE et al., "Binding Characteristics of N-Acetylglucosamine-Specific Lectin of the Isolated Chicken Hepatocytes: Similarities to Mammalian Hepatic Galactose/N-Acetylgalactosamin -Specific Lectin," <i>Biochem.</i> , 28: 8351-8358 (1989).		
X	FM	LEE, "Binding Modes of Mammalian Hepatic Gal/GalNAc R eceptors," <i>Ciba Found. Symp.</i> , 145: 80-95 (1989).		



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Sheet 5 of 6

OTHER - NON PATENT LITERATURE DOCUMENTS

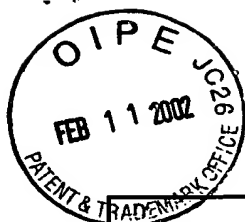
Translation

Yes No

Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Yes	No
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Substitute for form 1449A/B/PTO				Compl te if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	09/888,164
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				First Named Inventor	Ts'o et al.
				Group Art Unit	
				Examiner Name	
Sheet	6	of	6	Attorney Docket Number	212241
OTHER - NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation		
			Yes	No	
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